

Application No. 10/563,687  
Amendment dated August 1, 2008  
Reply to Office Action of May 1, 2008

Docket No. NY-GRYN 229-US

### REMARKS

Applicant respectfully submits that the references cited in the International Search Report of the claimed priority PCT application have been already submitted with the IDS filed on June 28, 2007 and considered by the Examiner in the present Office Action.

Specification has been objected for few minor informalities, i.e., missing page number and capitalization of the trademark term. Applicant has amended the specification to incorporate the Examiner's suggestion, accordingly, this objection to the specification should be withdrawn.

Application has been objected to for allegedly lacking abstract. Applicant kindly directs the Examiner to the fact that this application is a US national application of the international application no. PCT/EP2004/009242 and the abstract is already set forth on the cover page of this published international application. But, in order to expedite the prosecution of this application, the abstract has been rewritten in accordance with the Examiner's suggestion. Accordingly, applicant requests that this objection to the abstract be withdrawn.

Claims 1-9 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claim 2 has been canceled, thereby obviating the rejection to this claim. As with respect to the remaining claims, applicant has amended claims 1, 5 and 7 to overcome the Examiner's objections and to incorporate the Examiner's suggestion. It is respectfully requested that this rejection be withdrawn.

Claims 1-9 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by published international application WO 96/40869 to Krider et al. (hereinafter "Krider"). Claim 2 has been canceled and incorporated into amended claim

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1, thereby obviating this rejection to claim 2. With respect to the remaining claims, applicant respectfully traverses this rejection.

A rejection based on 35 U.S.C. § 102 requires that the cited reference disclose each and every element covered by the claim. *Electro Medical Systems S.A. v. Cooper Life Sciences Inc.*, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994); *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766, 1767-68 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988); *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2D 1051, 1053 (Fed. Cir.), *cert. denied*, 484 U.S. 827 (1987). The Federal Circuit has mandated that 35 U.S.C. § 102 requires no less than "complete anticipation ... [a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." *Connell v. Sears, Roebuck & Co.*, 772 F.2d 1542, 1548, 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983); *See also, Electro Medical Systems*, 32 U.S.P.Q. 2d at 1019; *Verdegaal Bros.*, 814 F.2d at 631.

Applicant respectfully submits that the present invention relates to a method for diagnosing intolerance by a subject to a specified substance. The object of the invention is to provide such a method which is more reliable and, especially, faster than the existing methods (see specification, page 2, line 31, and page 3, line 30 to page 4, line 4). The present invention provides such reliable and faster method by utilizing polymorphonuclear neutrophils (PMNs), which tend to become more adhesive on activation. In particular, the activated PMNs tend to adhere to plastic surfaces. Accordingly, the present invention diagnoses a subject's food intolerance based on a number of PMN activations. The number of PMN activations can be determined by measuring the number of PMNs adhering to a plastic surface after exposure to a specified substance, such as a food extract.

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Whereas, Krider describes a method for screening infectious diseases early in the course, since there is a substantial difference in surface binding of PMNs between infected and noninfected animals. The abstract of Krider, cited by the Examiner, merely recites that:

“This binding response can be rapidly and accurately distinguished and quantitated using various detection techniques. The method involves visualizing the surface binding of the cultured infectious agent to naturally-occurring PMNs to detect the infection.”

Accordingly, Krider merely describes detecting the binding of PMNs to pathogens, and contrary to the Examiner's assertion, Krider does not teach or suggest detecting/determining the overall activation of PMNs by detecting the adhesion/binding of PMNs to a plastic surface, such as plastic multi-well titre plate, as required in the claims of the present invention.

“To imbue one of ordinary skill in the art with knowledge of the present invention, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim of the insidious effect of hindsight syndrome, wherein that which only the inventor taught is used against the teacher.” *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983). Here, Krider does not teach or suggest a method of detecting a subject's food intolerance by determining the overall activation of PMNs by detecting the adhesion/binding of PMNs to a plastic surface, as required in claims 1 and 3-9 of the present invention. In fact, page 8, lines 22-27 in Krider, cited by the Examiner, merely describes only direct adhesion/binding of PMNs to the target substance:

“An appropriate method (e.g., fluorescence microscopy) is then utilized to observe the degree of binding of the foreign substance to the white blood cells. The degree of binding can indicate exposure to, or the presence of, the foreign substance, especially when compared to a control.”

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Applicant respectfully submits that the Examiner cannot use hindsight gleaned from the present invention to modify the clear teaching of the prior art reference to render claims unpatentable. The prior must to be judged based on a full and fair consideration of what that art teaches, not by using Applicant's invention as a blueprint for gathering various bits and modifying the pieces in an attempt to reconstruct Applicant's invention. The Examiner cannot simply change the principle of the operation of the reference or render the reference inoperable for its intended purpose to render the claims unpatentable. Accordingly, it is submitted that the Examiner has succumbed to the lure of prohibited hindsight reconstruction.

Moreover, Krider recites that the detection is carried out using "various detection techniques" or an "appropriate method" (see Krider at page 8, lines 1-3), but Krider fails to teach or suggest any method other than an optical method, such as fluorescence microscopy (Krider at page 13, lines 15-35).

Further, the claimed invention defined by the claims eliminates the shortcomings and disadvantages encountered with the prior art. Specifically, the claimed invention provides a reliable and efficient method of diagnosing a subject's food intolerance by measuring the number of PMN activations by detecting the adhesion/binding of PMNs to a plastic surface. Krider is not even remotely directed to the problem solved by the present invention.

Absent evidence that the specific problem of providing a reliable and efficient method of diagnosing a subject's food intolerance by measuring the number of PMN activations by detecting the adhesion/binding of PMNs to a plastic surface was even recognized by the prior art, there can be no finding that the invention as a whole would have been obvious. As stated by the PTO Board of Appeals in *Ex parte Breidt and Lefevre*, 161 U.S.P.Q. 767, 768 (1968), "an inventive contribution can reside as well in

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the recognition of a problem as in a solution". It further appears that the conclusion reached by the Board of Appeals in *Ex parte Minks*, 169 U.S.P.Q. 120 (1969), is here in point. There, the Board concluded that "[a]ppellant having discovered the source of the problem and solved the same ... he is ... entitled to patent protection". *Id.* at 121.

Since applicant has recognized a problem not addressed by the cited prior art and solved that problem in a manner not suggested by either Bardy or Pence, the basis for patentability of the claims is established. See *In re Wright*, 6 U.S.P.Q. 2d, 1959, 1961-1962 (Fed. Cir. 1988). There, the CAFC relied upon previous decisions requiring a consideration of the problem facing the inventor in reversing the Examiner's rejection. "The problem solved by the invention is always relevant". *Id.* at 1962. See also, *In re Rinehart*, 189 U.S.P.Q. 143, 149 (C.C.P.A. 1967), which stated that the particular problem facing the inventor must be considered in determining obviousness.

In view of the foregoing, it is respectfully submitted that the Examiner has failed to establish a *prima facie* case of anticipation or obviousness because Krider fails to teach or suggest a reliable and efficient method of diagnosing a subject's food intolerance by measuring the number of PMN activations by detecting the adhesion/binding of PMNs to a plastic surface. Accordingly, Applicant respectfully submits that pending claims 1 and 3-9 are not anticipated nor rendered obvious by Krider, and therefore, the pending claims 1 and 3-9 are in condition for allowance.

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Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. NY-GRYN 229-US (10601562) from which the undersigned is authorized to draw.

Respectfully submitted,

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